K112412

DEC 23 2011

510(k) Summary
AU5800 Clinical Chemistry Analyzer

1.0 Submitted By:

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2.0 Date Submitted

August 19, 2011

3.0 Device Name(s):

3.1 Proprietary Names

AU5800 Clinical Chemistry Analyzer

3.2 Classification Name

Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 Legally Marketed Device

Candidate(s)	Predicate	Manufacturer	Document Number
AU5800 Clinical Chemistry Analyzer	AU2700 Clinical Chemistry Analyzer	Beckman Coulter, Inc.	K002982

The AU5800 Clinical Chemistry Analyzer is substantial equivalence to the AU2700 Clinical Chemistry Analyzer (Docket Number K002982), currently in commercial distribution.

5.0 Device Description

The AU5800 clinical chemistry analyzer is a fully automated, random access analyzer, designed for ultra-high throughput laboratories. This system is designed to suit varying workloads and is available in different configurations, from a one-single photometric module AU5810, up to a four-photometric module AU5840. The AU5800 analyzer measures analytes in samples using the same reagents, calibrators, quality control (QC) materials and other consumables used within the AU series of instruments. This ensures the same reliable results and references ranges across the AU family members. This system carries out automated analysis of serum, plasma, urine samples and other body fluids and automatically generates results. Electrolyte measurement is performed using a single or double cell Ion Selective Electrode (ISE) which is also common among the other members of the AU family.

6.0 Intended Use

The Beckman Coulter AU5800 Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro

diagnostic use only. Applications include colorimetric, turbidimetric, latex agglutination, homogeneous enzyme immunoassay, and ion selective electrode.

7.0 Comparison to the Predicate

The AU5800 Clinical Chemistry System is a family member of the AU series of analyzers, including the AU2700 (K002982) to which the substantial equivalence comparison is claimed. The devices have same / similar design and modes of operation. The key features are summarized in the following table.

Feature	Predicate Device: AU2700 Clinical Chemistry System	Proposed Device: AU5800 Clinical Chemistry Analyzer
Intended Use:	The Olympus AU2700 Clinical Chemistry Analyzer is a fully automated photometric analyzer intended for clinical laboratory use. Applications include colorimetric, Turbidimetric, latex agglutination, and homogeneous enzyme immunoassay.	The Beckman Coulter AU5800 Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, turbidimetric, latex agglutination, homogeneous enzyme immunoassay, and ion selective electrode.
Methodology:	Analyzer, chemistry (photometric, discrete), for clinical use has been classified as Class I, JJE by the Clinical Chemistry and Clinical Toxicology Devices Panel, (21 CFR 862.2160).	Same as AU2700
Sample Types:	Blood serum, urine, CSF, or Plasma	Same as AU2700
Assay Type:	End Point, Kinetic, Ions Selective Electrode (ISE) Optional. Applications: Colorimetric, Turbidimetric, Latex Agglutination, Homogenous EIA.	Same as AU2700
Reactant Volume:	120µl to 430µl	80µl to 287µl
Sample Volume	1.6uL to 25.0 uL	1.0 to 17.0 uL
Prevention of Sample Carry Over	Deionized Water Wash with Contamination Avoidance Parameters and enhanced washing sequence	Same as AU2700 New function: extra optional DI wash sequence
Recognition of Sample	Read from the barcode	Same as AU2700
Reagent On-board chemistries	Reagent 1 – 48 bottle capacity Reagent 2 – 48 bottle capacity	Reagent 1 – 54 bottle capacity Reagent 2 – 54 bottle capacity
Reagent Bottle	Reagent bottles with a capacity of 15mL, 30 mL, 60 mL,120mL, 180mL	Same as AU2700
Reagent Volume Normal Pipette	15 to 250 µL (can be set by 1uL)	10 to 170 µL (can be set by 1uL)

Feature	Predicate Device: AU2700 Clinical Chemistry System	Proposed Device: AU5800 Clinical Chemistry Analyzer
Diluent Volume	0,10 to 235 uL (can be set by 1uL) Max (reagent+diluent) less than 250uL	0,10 to 160 uL (can be set by 1uL) Max (reagent+diluent) less than 170uL
Wave length (nm)	Halogen Lamp 340 to 800 nm 13 wavelengths: 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750 and 800 nm	Same as AU2700
Cuvette	Square, glass cuvette 6x5 mm (Inside) Capacity: 750 uL Light Path: 6mm	Square, glass cuvette 4 x 5 mm (Inside) Capacity: 500 uL Light Path: 5mm
Cycle time of photometry measuring point	28 points in 8.5 minutes (±.5 min)	Same as AU2700

Comparison testing

In order to further demonstrate the comparability of the Beckman AU2700 and the proposed new Beckman Coulter AU5800, the following reagent performance testing was performed on a representative number of assays:

Linearity
Precision
Method Comparison
Sensitivity
Interference
Reference Range

The AU5800 chemistry analyzer uses same Ion Selective Electrode (ISE) and reagents, as well as the same menu of reagents currently available on the AU2700. Representative assays from the AU chemistry menu were selected to demonstrate equivalency between the proposed AU5800 and the predicate device. The studies were selected from reviewing the applicable sections of FDA's eSubmitter software tool for instrument only submissions and utilizing the FDA's Guidance for Industry and FDA staff Replacement Reagent and Instrument Family Policy.

The remaining reagent application validations not presented within the 510(k) will be validated using risk management, design controls, and the principles from FDA's Guidance for Industry and FDA staff Replacement Reagent and Instrument Family Policy. The core validation principles are linearity, control/standard recovery, method comparison, precision, sensitivity, interference, prozone tolerance and on-board/calibration frequency studies. Reference ranges will be verified, where appropriate. No reagent application will be released to the market without the satisfactory completion of the validation process.

8.0 Summary of Performance Data

The submission provides the data necessary to demonstrate this equivalence based on the performance validations and comparisons conducted between the representative reagents and analyzer platforms. Based on this data, the new AU5800 Chemistry Analyzer is substantially equivalent to the referenced predicate(s).

Traceability

The traceability information in the reagent 510ks was updated via K043460 on the calibrator to align with the current IFU claims.

Predicate Reagent 510k(s)	Calibrator 510(k)	Current IFU claim
Glucose traceability NIST SRM 916a	Glucose traceability NIST SRM 965a	Glucose traceability NIST SRM 965a
Magnesium traceability NIST SRM 909a-2	Magnesium traceability NIST SRM 909b	Magnesium traceability NIST SRM 909b
Potassium traceability Not specified – but gravimetrically prepared standard	Not impacted by modification	Potassium traceability Not specified – but gravimetrically prepared standard

The on-board claims were re-assessed on the AU2700 analyzer 510k, which is the predicate for the AU5800. In addition, the potassium on board claims were expanded through the design control process.

Predicate Reagent 510(k)	AU2700 Instrument K003721	Current IFU
Glucose on-board stability 14 days	Glucose on-board stability 30 days	Glucose on-board stability 30 days
Magnesium on-board stability 30 days	Magnesium on-board stability 7 days	Magnesium on-board stability 7 days
Potassium on-board stability 30 days	Not mentioned in submission	Potassium on-board stability 90 days

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Beckman Coulter, Inc.
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DEC 23 2011

Re: K112412
Trade name: AU5800 Clinical Chemistry Analyzer

Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CFR, CEM, JGJ, JJE
Dated: November 11, 2011
Received: November 14, 2011

Dear Mr. Davis,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (k112412):

Device Name: AU5800 Clinical Chemistry Analyzer

Indication For Use:

The Beckman Coulter AU5800 Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes such as Glucose, Magnesium, and Potassium in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, turbidimetric, latex agglutination, homogeneous enzyme immunoassay, and ion selective electrode.

The Glucose test system is for the quantitative measurement of glucose in human serum, plasma, urine and cerebrospinal fluid on Beckman Coulter AU analyzers. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The Potassium test system is for the quantitative measurement of potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

The Magnesium test system is for the quantitative measurement of Magnesium in human serum, plasma and urine on Beckman Coulter AU analyzers. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).

Prescription Use ___X___ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k112412